

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1. (currently amended) A method for making composite active particles for ~~use in a pharmaceutical composition for~~ pulmonary inhalation, the method comprising the step of jet milling active particles in the presence of particles of additive material and,
~~optionally, air or a compressible gas or fluid.~~

Claim 2. (currently amended) A method as claimed in claim 1, wherein the additive material ~~comprises~~ is selected from the group consisting of: an amino acid, a metal stearate ~~or~~ and a phospholipid.

Claim 3. (currently amended) A method as claimed in claim 2, wherein the additive material ~~comprises one or more of~~ is selected from the group consisting of: leucine, isoleucine, lysine, valine, methionine, phenylalanine, and a combination of any of the foregoing.

Claim 4. (currently amended) A method as claimed in claim 3, wherein the additive material comprises one of the following: leucine and ~~preferably~~ L-leucine.

Claim 5. (original) A method as claimed in claim 2, wherein the additive material comprises magnesium stearate.

Claim 6. (original) A method as claimed in claim 2, wherein the additive material comprises lecithin.

Claim 7. (currently amended) A method as claimed in ~~any one of the preceding claims~~ claim 1, wherein the step of jet milling is carried out at an inlet pressure of between 0.1 and 3 bar.

Claim 8. (currently amended) A method as claimed in ~~any one of claims 1-6~~ claim 1, wherein the step of jet milling is carried out at an inlet pressure of between 3 and 12 bar.

Claim 9. (currently amended) A method as claimed in ~~any one of the preceding claims~~ claim 1, wherein at least 90% by volume of the active particles are less than 20µm in diameter prior to the step of jet milling.

Claim 10. (currently amended) A method as claimed in ~~any one of the preceding claims~~ claim 1, wherein at least 90% by volume of the additive particles are less than 20µm in diameter prior to the step of jet milling.

Claim 11. (currently amended) A method as claimed in ~~any one of the preceding claims~~ claim 1, wherein the step of jet milling is carried out at temperatures below room temperature.

Claim 12. (currently amended) A method as claimed in claim 11, wherein the step of jet milling is carried out at a temperature below 10°C ~~and preferably below 0°C~~.

Claim 13. (currently amended) A method as claimed in ~~any one of the preceding claims~~ claim 1, wherein the step of jet milling further comprises jet milling carrier particles ~~are also jet milled~~ with the active particles and the particles of additive material.

Claim 14. (original) A method as claimed in claim 13, wherein the carrier particles have a particle size of at least 20µm.

Claim 15. (currently amended) A method as claimed in claim 13, wherein the carrier particles have a particle size of less than 30 μ m, ~~preferably less than 20 μ m and more preferably less than 10 μ m.~~

Claim 16. (currently amended) A pharmaceutical composition comprising Composite composite active particles for use in a pharmaceutical composition made using a prepared in accordance with the method as claimed in any one of the preceding claims claim 1.

Claim 17. (currently amended) The pharmaceutical composition of claim 16, wherein said Composite active particles as claimed in claim 16, composition is for pulmonary inhalation.

Claim 18. (currently amended) The pharmaceutical composition of claim 16, Composite active particles as claimed in either of claims 16 and 17, wherein the additive material forms a coating on the surface of the additive composite particles.

Claim 19. (currently amended) The pharmaceutical composition of claim 18, Composite active particles as claimed in claim 18, wherein the coating is a discontinuous coating.

Claim 20. (currently amended) The pharmaceutical composition of claim 18, Composite active particles as claimed in either of claims 18 and 19 wherein the coating of additive material is not more than 1 μ m in thickness.

Claim 21. (currently amended) The pharmaceutical composition of claim 16, wherein said Composite composite active particles as claimed in any one of claims 16-20 having have an MMAD of not more than 10 μ m.

Claim 22. (currently amended) The pharmaceutical composition of claim 21, wherein said Composite composite active particles as claimed in claim 21, having have an MMAD of not more than 5 μ m, not more than 3 μ m, not more than 2 μ m, or not more than 1 μ m.

Claim 23. (currently amended) The pharmaceutical composition of claim 16, Composite active particles as claimed in any one of claims 16-22, wherein at least 90% by weight of the composite active particles have a diameter of not more than 10 μ m.

Claim 24. (currently amended) The pharmaceutical composition of claim Composite active particles as claimed in claim 23, wherein at least 90% by weight of the particles have a diameter of not more than 5 μ m, ~~not more than 3 μ m, or not more than 1 μ m.~~

Claims 25-26 (cancelled)

Claim 27. (currently amended) A composition as claimed in ~~either of claims 25 and 26~~ claim 16, wherein the composition is a dry powder composition.

Claim 28. (currently amended) A composition as claimed in claim [27] 16, wherein the composition further comprises carrier particles.

Claim 29. (currently amended) A composition as claimed in ~~any one of claims 25-28~~, claim 16, wherein the composition has a FPF(ED) of at least 70%.

Claim 30. (currently amended) A composition as claimed in claim 29, wherein the FPF(ED) is at least 80%, ~~at least 85%, or at least 90%.~~

Claim 31. (currently amended) A composition as claimed in ~~any one of claims 25-28~~, claim 16, wherein the composition has a FPF(MD) of at least 60%.

Claim 32. (currently amended) A composition as claimed in claim 29, wherein the FPF(MD) is at least 70%, ~~at least 80%, or at least 85%.~~

Claim 33. (currently amended) A dry powder inhaler containing a composition as claimed in ~~any one of claims 25-32~~ claim 16.

Claim 34. (canceled)

Claim 35. (new) A method as claims in claim 1, wherein the step of jet milling active particles is carried out in the presence of particles of additive material and one of the following: air, compressible gas and fluid.

Claim 36 (new) A method according to claim 11, wherein the step of jet milling is carried out at a temperature below 0°C.

Claim 37. (new) A method as claimed in claim 13, wherein the carrier particles have a particle size of less than 20µm.

Claim 38. (new) A method as claimed in claim 13, wherein the carrier particles have a particle size of less than 10µm.

Claim 39. (new) A pharmaceutical composition as claimed in claim 21, wherein said composite active particles have an MMAD of not more than 1 µm.

Claim 40. (new) A pharmaceutical composition as claimed in claim 23, wherein at least 90% by weight of the particles have a diameter of not more than 1 µm.

Claim 41. (new) A composition as claimed in claim 29, wherein the FPF(ED) is at least 90%.

Claim 42. (new) A composition as claimed in claim 29, wherein the FPF(MD) is at least 85%.